UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

SHARON WORTMAN and THOMAS WORTMAN,	)	
Plaintiffs,	)	
vs.	)	No. 1:19-cv-03273-JMS-DLP
C.R. BARD, INC.,	)	
Defendant.	)	

ORDER

On August 5, 2019, Plaintiffs Sharon Wortman and Thomas Wortman (collectively, the "Wortmans") filed a Complaint against C. R. Bard, Inc. ("Bard"), seeking to recover damages for injuries Ms. Wortman alleges she sustained from the Align TO Urethral Support System ("Align") medical device that her physician implanted to treat her stress urinary incontinence. [Filing No. 1 at 1.] Presently pending before the Court are Bard's Motion to Dismiss, [Filing No. 10], and Motion for Oral Argument, [Filing No. 12]. Bard seeks dismissal pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. [Filing No. 11 at 10.] For the reasons that follow, the Court **GRANTS IN PART** and **DENIES IN PART** Bard's Motion to Dismiss. The parties' briefs afforded the Court an adequate basis on which to rule without the assistance of oral argument. The Court therefore **DENIES** Bard's Motion for Oral Argument, [Filing No. 12].

I.
LEGAL STANDARD

Federal Rule of Civil Procedure 8(a)(2) "requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief.'" *Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (quoting Fed. R. Civ. P. 8(a)(2)). "Specific facts are not necessary, the statement need

only 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Erickson*, 551 U.S. at 93 (quoting *Bell Atlantic v. Twombly*, 550 U.S. 544, 555 (2007)).

A motion to dismiss asks whether the complaint "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). In reviewing the sufficiency of a complaint, the Court must accept all well-pled facts as true and draw all permissible inferences in favor of the plaintiff. *See Active Disposal, Inc. v. City of Darien*, 635 F.3d 883, 886 (7th Cir. 2011). The Court will not accept legal conclusions or conclusory allegations as sufficient to state a claim for relief. *See McCauley v. City of Chicago*, 671 F.3d 611, 617 (7th Cir. 2011). Factual allegations must plausibly state an entitlement to relief "to a degree that rises above the speculative level." *Munson v. Gaetz*, 673 F.3d 630, 633 (7th Cir. 2012). This plausibility determination is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.*

II.
BACKGROUND

The following are the factual allegations set forth in the Wortmans' Complaint, which the Court must accept as true.

Bard is a company that "develops, designs, manufactures, labels, packages, distributes, markets, supplies, advertises, sells and develops technology to diagnose and treat conditions related to the pelvic health of women." [Filing No. 1 at 3.] One example of Bard's technology is the Align device. [Filing No. 1 at 3.] On or about July 8, 2009, Ms. Wortman underwent implant surgery with her physician in Beech Grove, Indiana to have the Align device implanted following a hysterectomy performed on the same day by a different physician. [Filing No. 1 at 6.] "Years after the implant," Ms. Wortman began to experience various adverse effects including: "vaginal

pain, infections, lower abdominal pain, dyspareunia[,]. . . urinary infections[,] . . . [and] incontinence problems." [Filing No. 1 at 6.] Ms. Wortman was examined by a physician and "was diagnosed with uterovaginal prolapse, stress urinary incontinence and a grade III cystocele," which caused Ms. Wortman to experience pain, bleeding, and the recurrence of her original medical problems. [Filing No. 1 at 6.] The adverse effects that Ms. Wortman experienced resulted in her having to attend multiple doctor appointments and impaired her ability to carry on with her daily activities including gardening and household chores. [Filing No. 1 at 6.] On or about August 4, 2017, Ms. Wortman underwent a procedure to have the Align device removed. [Filing No. 1 at 6.]

The Align device has defective characteristics that caused Ms. Wortman's injuries. [Filing No. 1 at 6.] The defective characteristics include: "using polypropylene mesh, using mesh designed with inadequate pore sizes, using mesh with inadequate thickness and using named predicate devices that were recalled or cleared under Federal Drug Administration's 510(k) process." [Filing No. 1 at 6-7.] Ms. Wortman and her treating physician were exposed to advertisements and marketing for the Align device, and Bard intended that Ms. Wortman and her physician would rely on this information. [Filing No. 1 at 7.] Bard's marketing contained misrepresentations and omissions regarding the Align device's safety, viability, and use, and Ms. Wortman and her physician decided to have the Align device implanted based on these misrepresentations and omissions. [Filing No. 1 at 7.] The Align device "was never adequately tested and never approved by the FDA for sale." [Filing No. 1 at 19.] Bard knew or should have known that there would be serious complications and side effects of implanting the Align device, but Bard failed to mitigate these problems and continued to sell the Align device. [Filing No. 1 at 20.] Had Ms. Wortman's physician known about the Align device's defects and likelihood for

causing adverse effects, he would have chosen a different, much safer alternative procedure for Ms. Wortman. [Filing No. 1 at 21.]

The Wortmans set forth the following claims against Bard in their Complaint:

- Count I: Negligence
- Count II: Strict Liability – Design Defect
- Count III: Strict Liability – Manufacturing Defect
- Count IV: Strict Liability – Failure to Warn
- Count V: Strict Liability – Defective Product
- Count VI: Breach of Express Warranty
- Count VII: Breach of Implied Warranty
- Count VIII: Discovery Rule, Tolling, and Fraudulent Concealment
- Count IX: Negligent Misrepresentation
- Count X: Negligent Infliction of Emotional Distress
- Count XI: Gross Negligence
- Count XII: Unjust Enrichment
- Count XIII: Factual Basis for Punitive Damages

[Filing No. 1.]

On September 27, 2019, Bard filed its Motion to Dismiss, arguing that: (1) all of the Wortmans' claims are subsumed by the Indiana Products Liability Act ("IPLA"); (2) the IPLA's statute of repose bars all of the Wortmans' claims; and, (3) all of the Wortmans' claims are deficient in one way or another and must be dismissed. The Motion to Dismiss is ripe for the Court's decision.

III.
DISCUSSION

In their Response, the Wortmans make several concessions. Before the Court turns to the merits of each of Bard's arguments in support of its Motion to Dismiss, the Court will first address the Wortmans' concessions, as these concessions resolve many issues raised in Bard's Motion to Dismiss. Then, the Court will address, in turn, each remaining issue raised in the Motion to Dismiss.

A. Concessions by the Wortmans

1. Breach of Warranty Claims (Counts VI and VII)

Although "*some* breach of warranty claims are subsumed by the IPLA and *some* are not," *Cavender v. Medtronic, Inc.*, 2017 WL 1365354, at *6 (N.D. Ind. Apr. 14, 2017) (emphasis in original), the Wortmans concede that the breach of warranty claims they raise in Counts VI and VII of their Complaint are based in tort and, therefore, are subsumed by the IPLA. Therefore, the Court need not address Bard's arguments regarding vertical privity[1] and pre-suit notice, which are both requirements of contract-based breach of warranty claims. Accordingly, Bard's Motion to Dismiss on this point is **DENIED as moot**. Below, the Court will examine whether these claims may proceed under the Wortmans' IPLA claim.

2. Counts XI, XII, and XIII

In their Response, the Wortmans concede that certain claims in their Complaint cannot succeed. [Filing No. 20 at 24.] Those claims are Count XI (Gross Negligence), Count XII (Unjust Enrichment), and Count XIII (standalone claim for punitive damages). [Filing No. 20 at 24.]

[1] "The [IPLA] does not require a personal injury plaintiff to prove vertical privity in order to assert a products liability claim against the manufacturer." *Hyundai Motor Am., Inc. v. Goodin*, 822 N.E.2d 947, 954 (Ind. 2005).

Therefore, Bard's Motion to Dismiss as it relates to these counts is **GRANTED**, and those counts are **DISMISSED WITH PREJUDICE**.

3. Negligent Misrepresentation

The Wortmans also concede that they did not have a business transaction with Bard. [Filing No. 20 at 24.] Indiana law only permits a claim of negligent misrepresentation in certain contexts wherein the defendant "supplies false information for the guidance of others in their business transactions," among other required elements. *Eby v. York-Div., Borg-Warner*, 455 N.E.2d 623 (Ind. Ct. App. 1983). Because the Wortmans concede that there was no business transaction with Bard, Bard's Motion to Dismiss related to this count is **GRANTED**, and the Wortmans' claim for Negligent Misrepresentation (Count IX) is **DISMISSED WITH PREJUDICE**. *See Lautzenhiser v. Coloplast A/S*, 2012 WL 4530804, *6 (S.D. Ind. Sept. 29, 2012) (dismissing negligent misrepresentation claim from product liability case because there was no business transaction).

4. Defective Product and Negligent Infliction of Emotional Distress

In their Response, the Wortmans concede that their Strict Liability – Defective Product claim (Count V) and their Negligent Infliction of Emotional Distress claim (Count X) are subsumed by the IPLA. Below, the Court will examine whether the Wortmans have sufficiently stated a claim for the theories of strict liability for a defective product and negligence and whether they can proceed with those theories within the scope of their IPLA claim.

5. Loss of Consortium

Finally, the Wortmans concede that their Complaint "did not contain a claim for loss of consortium on behalf of Thomas Wortman." [Filing No. 20 at 24.] However, the Wortmans express their desire to amend their Complaint to allow them to properly raise a loss of consortium claim. [Filing No. 20 at 24.]

In light of the Wortmans' concession, Bard's Motion to Dismiss as to this issue is **GRANTED insofar as the original complaint contained no such claim**, so Thomas Wortman, is **DISMISSED WITHOUT PREJUDICE** as a plaintiff.[2] Should the Wortmans amend their Complaint to properly assert a loss of consortium claim on behalf of Mr. Wortman, the Court notes that such a claim would not be subsumed by the IPLA because it is a derivative cause of action. *Jarrett v. Wright Medical Tech., Inc.*, 2019 WL 2567708, *5-6 (S.D. Ind. June 21, 2019).

B. Amendment of Complaint

In their Response, the Wortmans seek leave to file an Amended Complaint. Bard challenges the Wortmans' attempt to get permission to amend their Complaint, arguing that a Response brief is not the correct vehicle to amend their Complaint and the Wortmans did not timely exercise their right to amend the Complaint. [Filing No. 25 at 1.] Moreover, Bard argues, an amendment of the Complaint would be futile because all of the Wortmans' claims are time-barred by the IPLA's statute of repose. [Filing No. 25 at 2.]

[2] The Court will dismiss Mr. Wortman as a party without prejudice; however, the Court admonishes the Wortmans that it could have chosen to make the dismissal with prejudice, just as the Court did in *Bailey v. Medtronic, Inc.*, 2017 WL 6035329, *6 n.2 (S.D. Ind. Dec. 6, 2017) ("Here, the Baileys chose not to revise their allegations[—pursuant to Federal Rule of Civil Procedure 15(a)(1)(B)—]relating to Count IV despite being aware of Defendant's arguments in support of dismissal and chose instead to brief the current Motion to Dismiss and adjudicate the issues. The Court is not required to give the Baileys another chance to plead their breach of warranty claim and in its discretion, the Court dismisses Count IV of the Complaint with prejudice."). The Court also warns that the Wortmans' decision to file a brief in response to the Motion to Dismiss and then, in the text of brief, ask the Court for leave to amend their Complaint may be a situation that could warrant the application of sanctions. *See* 28 U.S.C. § 1927 ("Any attorney . . . who so multiplies the proceedings in any case unreasonably and vexatiously may be required by the court to satisfy personally the excess costs, expenses, and attorneys' fees reasonably incurred because of such conduct."). If the Wortmans had instead filed an Amended Complaint in response to the Motion to Dismiss, the Court could have avoided spending time and resources addressing Bard's Motion to Dismiss.

The Court disagrees regarding the futility of an amendment to the Wortmans' Complaint, as discussed below. Further, the Wortmans' failure to include allegations regarding a loss of consortium claim was obviously an oversight. Although Local Rule 7-1 requires that a Motion to Amend be filed separately, the Court will permit the Wortmans to file an Amended Complaint **on or before December 10, 2019** consistent with the rulings contained herein.

C. Statute of Repose

Bard's first argument in support of its Motion to Dismiss relates to the IPLA's statute of repose. Bard argues that all of the Wortmans' claims are time-barred by the statute of repose, because the Wortmans filed their Complaint more than ten years after Ms. Wortman had the Align device implanted. [Filing No. 11 at 11.] Bard argues that the statute of repose's sole exception does not apply to this case because Ms. Wortman's cause of action accrued before eight years had passed from the date she was implanted with the Align device. [Filing No. 11 at 12.] Furthermore, Bard argues, the Wortmans cannot rely on the discovery rule or other tolling doctrines because the IPLA's statute of repose cannot be tolled. [Filing No. 11 at 13.]

In response, the Wortmans argue that Bard "cannot expect [them] to know if a device is unsafe to be used as intended," and they "would have no way to know if a device is defective" and would instead have to rely on Bard's "misstatements and omissions." [Filing No. 20 at 8 (quoting Filing No. 1 at 52).] The Wortmans argue that no due diligence on their part would have led them to the discovery of the Align device's defects. [Filing No. 20 at 8-9.] Therefore, the Wortmans argue, their claims are not time-barred by the statute of repose because they filed their Complaint within two years of the August 4, 2017 surgery to remove the implant. [Filing No. 20 at 9-10.] The Wortmans argue that the Complaint was timely filed on August 5, 2019 (which was the next

business day following the August 4, 2019 deadline for the two-year statute of limitations). [Filing No. 20 at 10.]

In reply, Bard argues that the Wortmans' suggestion that the date of accrual of their claim is August 4, 2017 is not reasonable because it is highly unlikely that Ms. Wortman was unaware of any problems with the Align device within the first eight years she had it. [Filing No. 25 at 4.] Pointing to the Complaint, Bard notes that the Wortmans allege Ms. Wortman began experiencing complications "years" after the Align device was implanted, so it is clear that their claims arose sooner than the Wortmans are now alleging in their Response. [Filing No. 25 at 4.] Further, Bard argues, it is not reasonable to infer that Ms. Wortman first discovered her injuries on August 4, 2017, and that same day she "experience[ed] her complications, received a diagnosis, and had surgery" to remove the Align device. [Filing No. 25 at 4.] Furthermore, Bard argues, "the FDA had distributed informational material on numerous occasions disclosing the complications related to mesh products," so the Wortmans cannot claim that no due diligence on their part would have uncovered the alleged defects in the Align device. [Filing No. 25 at 5.]

The IPLA provides:

> [A] product liability action must be commenced:
>
> (1) within two (2) years after the cause of action accrues; or
> (2) within ten (10) years after the delivery of the product to the initial user or consumer.
>
> However, if the cause of action accrues at least eight (8) years but less than ten (10) years after the initial delivery, the action may be commenced at any time within two (2) years after the cause of action accrues.

Ind. Code § 34-20-3-1(b).

Ms. Wortman's physician implanted the Align device on July 8, 2009. Ms. Wortman states in her Complaint that "[y]ears after the implant," she started to experience physical issues and she "was diagnosed with uterovaginal prolapse, stress urinary incontinence and a grade III cystocele.

. . ." [Filing No. 1 at 6.] On August 4, 2017, Ms. Wortman had the Align device removed. The Wortmans filed their Complaint on August 5, 2019.

The ten-year deadline from the date the Align device was implanted is July 8, 2019. If the date of implantation is the proper date for calculating the statute of repose, then the Wortmans' IPLA claims would clearly be time-barred. If, however, the date that Ms. Wortman's injury was or should have been discovered is August 4, 2017—the date the Align device was removed—then the two-year deadline from that date would fall on August 4, 2019. However, because August 4, 2019 was a Sunday, the following business day (August 5, 2019) is the operative deadline for filing the Complaint, *see* Fed. R. Civ. P. 6(a)(3)(A)—and this was the date on which the Wortmans filed their Complaint.

A plaintiff is not required to plead facts that overcome affirmative defenses based on the statute of limitations. *NewSpin Sports, LLC v. Arrow Elecs., Inc.*, 910 F.3d 293, 299 (7th Cir. 2018). Accordingly, dismissing a complaint as untimely based on the pleadings is disfavored, as a statute of limitations defense greatly turns on facts not before the Court at this stage. *See Sidney Hillman Health Ctr. of Rochester v. Abbott Labs., Inc.*, 782 F.3d 922, 928 (7th Cir. 2015) (citations omitted). A statute of limitations or statute of repose "begins to run from the date that the plaintiff knew or should have discovered that she suffered an injury or impingement, and that it was caused by the product or act of another." *Nelson v. Sandoz Pharms. Corp.*, 288 F.3d 954, 966 (7th Cir. 2002) (quoting *Degussa Corp. v. Mullens*, 744 N.E.2d 407, 410 (Ind. 2001)). "As long as there is a conceivable set of facts, consistent with the complaint, that would defeat a statute-of-limitations defense, questions of timeliness are left for summary judgment (or ultimately trial), at which point the district court may determine compliance with the statute of limitations based on a more complete factual record." *Sidney*, 782 F.3d at 928.

Here, although the Court agrees that the Wortmans may have a difficult time proving that Ms. Wortman only discovered (or should have discovered) her injuries on August 4, 2017, at this early stage of the proceeding, and accepting the allegations of the Complaint as true, the Court cannot discern when Ms. Wortman discovered, or should have discovered, her injury. Ms. Wortman alleges that she discovered her injury on August 4, 2017. Accepting this statement as true, the Court concludes that Bard's Motion to Dismiss based on the IPLA's statute of repose should be **DENIED.**

D. The IPLA

Because this Court is exercising diversity jurisdiction, it will apply the laws of Indiana. *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). Both parties agree that Indiana law applies and that the IPLA is the statute that governs products liability claims in Indiana.

Originally enacted in 1978 and expanded in 1995, the IPLA "codified the entire field of products liability" law in Indiana. *Weigle v. SPX Corp.*, 729 F.3d 724, 737 (7th Cir. 2013). The IPLA "governs all actions that are: (1) brought by a user or consumer; (2) against a manufacturer or seller; and (3) for physical harm caused by a product; regardless of the substantive legal theory or theories upon which the action is brought." Ind. Code § 34-20-1-1. "A product can be defective within the meaning of the [IPLA] because of a manufacturing flaw, a defective design or a failure to warn of the dangers while using the product." *Campbell Hausfeld/Scott Fetzer Co. v. Johnson*, 109 N.E.3d 953, 956 (Ind. 2018). The Indiana Supreme Court has stated that it is "clear the legislature intended that the [IPLA] govern all product liability actions, whether the theory of liability is negligence or strict liability in tort." *Dague v. Piper Aircraft Corp.*, 418 N.E.2d 207, 212 (Ind. 1981).

E. Pleading Under the IPLA[3]

District courts in Indiana have taken different approaches when they determine that individual tort claims pled in a complaint are subsumed by the IPLA: some courts have decided to "merge" the tort claims into the single IPLA claim, while other courts have chosen to dismiss the tort claims to allow the plaintiff to replead a single IPLA count that includes the plaintiff's various theories of recovery under the IPLA. Most district courts in Indiana previously followed the "merging" approach. However, within the last few years, the Northern District of Indiana has held that merger was "unnecessary" at the pleading stage because "[w]hether the theories are designated as Counts 1 through 6, or Count 1(a) through 1(f), both parties understand that [the plaintiff] is pursuing a single cause of action under the IPLA" and "if anything, breaking the different theories into separate counts made the complaint easier to understand." *Fisk v. Medtronic, Inc.*, 2017 WL 4247983, *4 (N.D. Ind. Sept. 25, 2017).

This Court agrees with the Northern District's reasoning in *Fisk*: whether each of the Wortmans' product liability counts are merged into one count or maintained in separate counts of the Complaint is largely a distinction without a difference. Indiana law provides multiple theories of recovery for products liability under the IPLA, and the Indiana Pattern Jury Instructions (Civil) contain separate pattern instructions for each theory.[4] Ind. Code § 34-20-4-1, *et seq.*; *Campbell,*

[3] One of the grounds of Bard's Motion to Dismiss is that the Wortmans failed to plead their claims under the IPLA. However, failure to cite the statute does not warrant dismissal. *See Bartholet v. Reishauer A.G. (Zurich)*, 953 F.2d 1073, 1078 (7th Cir. 1992) (A complaint "need not identify a legal theory, and specifying an incorrect theory is not fatal."). The Wortmans acknowledge that the IPLA is the proper vehicle for their product liability claims, and they argue all of their non-conceded claims fall within the scope of the IPLA and can proceed under a negligence theory and a strict liability theory under the IPLA.

[4] *See* Indiana Pattern Jury Instruction (Civil) Chapter 2100 (providing pattern instructions for manufacturing defects); Indiana Pattern Jury Instructions (Civil) Chapter 2300 (providing pattern instructions for design defects and the failure to warn).

109 N.E.3d at 956. So long as their allegations are sufficiently pled, the Wortmans can pursue each of the various theories of recovery under the IPLA—claims for manufacturing defects, design defects, and the failure to warn—and there is no sense in formally "merging" them into a single count in the Complaint.

In this case, the Wortmans brought several claims in which they, as consumers, seek to recover from Bard, as a manufacturer, for physical harm caused by a product, namely the Align device. Accordingly, those counts of the Wortmans' Complaint fall within the scope of the IPLA. Rather than dismiss the Complaint for failing to point to the appropriate statute (*i.e.*, the IPLA), the Court will analyze each claim to determine whether relief under the IPLA is plausible under any set of facts that could be established consistent with the allegations.

F. Theories Under the IPLA

The Wortmans allege the following tort-based claims against Bard: Negligence; Design Defect; Manufacturing Defect; Defective Product; Failure to Warn; Negligent Infliction of Emotional Distress; and Breach of Express and Implied Warranties.

Bard argues these claims are actually subsumed by the IPLA and should have been asserted as a single claim under the IPLA. [Filing No. 11 at 14.] Bard argues the Court should dismiss the Wortmans' Complaint because the single IPLA claim is improperly pled. [Filing No. 11 at 15.]

In response, the Wortmans argue that their claims can be brought under the IPLA in a negligence claim and they agree that all of their "strict liability claims are tort based and fall under the IPLA." [Filing No. 20 at 11-12.] They argue that they have adequately pled a negligence claim because they have pled "physical harm and injury caused by the defective Align device." [Filing No. 20 at 13-14.] The Wortmans also assert that they "should be afforded the chance to

amend their complaint to plead sufficient factual allegations and [their Complaint] should not be dismissed." [Filing No. 20 at 14.]

As explained above, the IPLA "governs all [product liability] actions. . . regardless of the substantive legal theory or theories upon which the action is brought," Ind. Code § 34-20-1-1, whether they are based on strict liability or negligence, *see Cook v. Ford Motor Co.*, 913 N.E.2d 311, 319 n.4 (Ind. Ct. App. 2009). "A product may be defective within the meaning of the [IPLA] because of a manufacturing flaw, a design defect, or a failure to warn of the dangers in the product's use." *Cook*, 913 N.E.2d at 319. "Cases alleging a failure to adequately warn under the [IPLA] sound in negligence," *id.*, "claims alleging a product design defect . . . [employ] a negligence standard," *TRW Vehicle Safety Systems, Inc. v. Moore*, 936 N.E.2d 201, 214 (Ind. 2010), and manufacturing defect claims are based on strict liability, *see Heritage Operating, L.P. v. Mauck*, 37 N.E.3d 514, 523 (Ind. Ct. App. 2015).

Based on this guidance, the Court finds that all of the Wortmans' tort-based claims are subsumed by the IPLA, with the exception of any claims that cannot survive the Motion to Dismiss and must be dismissed. The Court will assess each theory to determine if the Wortmans have sufficiently pled a claim upon which relief can be granted.

1. Negligence

As explained above, a negligence standard is used in claims of design defect and failure to warn. *Cook*, 913 N.E.2d at 319; *TRW*, 936 N.E.2d at 214. For design defect and failure to warn claims, "the party making the claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product or in providing the warnings or instructions." Ind. Code § 34-20-2-2. More generally, "[n]egligence claims have three elements: (1) a duty owed by the defendant to the plaintiff, (2) a breach of that duty and (3) injury to the

plaintiff proximately caused by the defendant's breach." *Hayden v. Franciscan Alliance, Inc.*, 131 N.E.3d 685, 693 (Ind. Ct. App. 2019).

Bard argues that the Wortmans' failure to warn claim is insufficient because it fails to explain what warning Bard allegedly gave, what Ms. Wortman's physician already knew, how the warning was inadequate, and that the physician would have refused to use the Align device had he had a proper warning. [Filing No. 25 at 7.]

In their Complaint, the Wortmans have alleged that Bard was "negligent in failing to use reasonable care in designing" the Align device, "failed to state adequate information in the labeling and packaging; and failed to use reasonable care in marketing and selling the Align omitting its known adverse effects and its high risk of complications and device failure with the possibility of the mesh needing to be removed." [Filing No. 1 at 28-29]. The Wortmans further allege that these failures caused Ms. Wortman to be injured and sustain damages. [Filing No. 1 at 30-31.] These allegations sufficiently state a product liability claim based on the theories of design defect and failure to warn, which are different theories of recovery under the IPLA, but properly raised here.[5]

However, this still leaves one additional argument from Bard to consider: whether the Wortmans' failure to warn claims must be dismissed under the "learned intermediary doctrine." The learned intermediary doctrine "holds that the manufacturer of a prescription drug or medical

[5] Count I of the Wortmans' Complaint is for a claim of "Negligence." However, as explained above, negligence is the standard that applies to product liability claims based on theories of design defect and failure to warn. Therefore, Count I is duplicative. The design defect and failure to warn theories shall proceed under the Wortmans' IPLA claim. The Wortmans' negligence claim survives inasmuch as negligence remains the standard for design defects and failure to warn. The same reasoning is not so clear as to Count X of the Wortmans' Complaint, which is a claim for Negligent Infliction of Emotional Distress. While this claim seeks relief for emotional damages resulting from a personal injury caused by a defective product, and should be considered as part of the Wortmans' IPLA claim, it is not, however, a standalone claim, and is therefore **DISMISSED WITH PREJUDICE**.

device fulfills its duty to warn of the product's risks by informing the prescribing physician of those risks." *In re Zimmer, NexGen Knee Implant Prods. Liab. Litig.*, 884 F.3d 746, 754 (7th Cir. 2018); *Gore v. Stryker Corp.*, 2011 WL 13324116, *1 (S.D. Ind. Jan. 20, 2011) ("Indiana has adopted the learned intermediary doctrine in medical device cases. Pursuant to this doctrine, a manufacturer's failure to warn about prescription products such as the Stryker pain pump extends only to the medical professional implanting it and not to the ultimate user like [plaintiff]."") (citations omitted).

Bard argues that the Wortmans' failure to warn claims must be dismissed under the learned intermediary doctrine because Bard owed no duty to warn consumers. [Filing No. 11 at 17.] The Wortmans argue that an exception to the learned intermediary doctrine applies here because Bard failed to provide sufficient warnings and instructions to Ms. Wortman's physician and Bard made assurances to Ms. Wortman, her physician, and the public that the Align device was safe and reasonably fit for its intended purpose. [Filing No. 20 at 16-17.]

While Bard may be correct that it owed no duty to warn consumers, the Complaint in this case extends beyond warning consumers, because the Wortmans explicitly allege that Bard failed to provide adequate knowledge of risks to Ms. Wortman "and/or her physician." [Filing No. 1 at 26.] Further, the Wortmans argue that the learned intermediary doctrine does not apply here because although "the manufacturer of a medical device had no duty to warn the patient" under the learned intermediary doctrine, the doctrine only applies if "the manufacturer provides *adequate* warnings to the physician." *Zimmer*, 884 F.3d at 750 (emphasis added). In their Complaint, the Wortmans assert that Bard failed to provide adequate warnings of the risks of the Align device to Ms. Wortman "and/or her physician." [Filing No. 1 at 26.] Therefore, the learned intermediary doctrine does not provide grounds to dismiss the Wortmans' failure to warn claims.

That said, Bard also argues that the Wortmans' failure to warn claim is deficient because "[t]he Complaint does not allege Bard failed to warn [Ms. Wortman's] health care providers of risks not already known to them." [Filing No. 11 at 17]; *see Minisan v. Danek Med., Inc.*, 79 F. Supp. 2d 970, 978 (N.D. Ind. 1999) ("[E]ven if the manufacturer provides inadequate information, however, the manufacturer will not be liable if the plaintiff's physician independently knew of the risks and failed to advise the plaintiff."). However, the Wortmans' allege in their Complaint that "[h]ad [the physician] known about [the] defects and severe complications [of the Align device], at the time he implanted the Align into Plaintiff Sharon Wortman, [the physician] would have opted for much safer alternatives. . . ." [Filing No. 1 at 21.] This allegation sufficiently sets forth the assertion that Ms. Wortman's physician was not independently aware of the risks of the Align device. Therefore, the Wortmans' failure to warn claim has been sufficiently pled.

For these reasons, Bard's Motion to Dismiss as it relates to the Wortmans' theories of design defect and failure to warn (and, inherently, negligence) is **DENIED**. Furthermore, the Motion to Dismiss as it relates to the Wortmans' Negligent Infliction of Emotional Distress claim (Count X) is **GRANTED**, and that claim is **DISMISSED WITH PREJUDICE**.

2. Strict Liability and Manufacturing Defect

Under Indiana law,

> A product manufacturer is liable under the following statutory terms:
>
> > (a) One who sells, leases, or otherwise puts into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer or to his property if that user or consumer is in the class of persons that the seller should reasonably foresee as being subject to the harm caused by the defective condition, and if:
> >
> > > (1) the seller is engaged in the business of selling such a product and

> (2) the product is expected to and does reach the user or consumer without substantial alteration in the condition in which it is sold by the person sought to be held liable under this chapter.

Ind. Code § 33-1-1.5-3(a).

In its Motion to Dismiss, Bard argues that the manufacturing defect claim (Count III) fails because the Wortmans do not allege that the Align device deviated from its intended design or had any defect from the manufacturing process. [Filing No. 11 at 16].

In response, the Wortmans argue that their manufacturing defect claim is sufficient under the IPLA because Bard "sold a product to Plaintiffs that caused Sharon Wortman severe injury that resulted in the removal of [Bard's] Align device." [Filing No. 20 at 14-15.]

In their Complaint, the Wortmans have alleged that: (1) Bard sold the subject Align device and is in the business of doing so, [Filing No. 1 at 2]; (2) the Align device is defective and unreasonably dangerous because it is toxic when it meets human tissue, [Filing No. 1 at 47]; (3) the defect is dangerous to foreseeable consumers, patients, and users (specifically here, women with stress urinary incontinence problems), [Filing No. 1 at 47]; (4) the Align device was "utilized and implanted in a manner foreseeable by [Bard] and was in the same or substantially similar condition as it was when it left [Bard's] possession, and in the condition directed by and expected by [Bard]," [Filing No. 1 at 27]; and, (5) "[a]s a direct and proximate result of the Align's" defects, Ms. Wortman was injured and the Wortmans sustained damages, [Filing No. 1 at 43]. Although, at this stage in the proceeding, it appears likely that the more appropriate theory of recovery may be a design defect (based on the pore size and material of the mesh), the Wortmans have sufficiently pled a theory of manufacturing defect. As recognized by the Seventh Circuit,

> the victim of a genuinely defective product—for example, an air bag that fails to inflate in a serious automobile collision, or an

> implantable cardiac defibrillator that delivers powerful electric shocks to a heart that is functioning normally—may not be able to determine without discovery and further investigation whether the problem is a design problem or a manufacturing problem. It is common, for example, for injured plaintiffs to plead both defective manufacture and defective design and to pursue discovery on both theories . . . [In addition,] in the context of Class III medical devices, much of the critical information is kept confidential as a matter of federal law.

Bausch v. Stryker Corp., 630 F.3d 546, 560 (7th Cir. 2010). At this stage, the Wortmans have pled sufficient allegations to survive a Rule 12(b)(6) motion and, therefore, the Wortmans may proceed with their IPLA claim under a theory of manufacturing defect.[6] Accordingly, Bard's Motion to Dismiss as it relates to the Wortmans' theory of manufacturing defect (and, inherently, strict liability for a defective product) is **DENIED**.

3. Breach of Express and Implied Warranties

The Wortmans also allege that Bard "made assurances . . . that the Align was safe and reasonably fit its intended purposes and intended uses," and Ms. Wortman "reasonably relied upon [Bard's] express warranties the device would work as intended." [Filing No. 1 at 48.] The Wortmans also allege that "[t]he Align implanted in [Ms.] Wortman never worked as intended and did not meet the industry standard guarantees a product will meet a certain level of quality and reliability nor was it suited to be used for its intended use as warranted and promoted by [Bard.]" [Filing No. 1 at 49.]

The Wortmans also allege that Bard "impliedly warranted the Align was merchantable and fit for the ordinary purposes for which it was intended and impliedly warranted that the product

[6] Count V of the Wortmans' Complaint is for a claim of "Strict Liability – Defective Product." As explained above, a manufacturing defect claim is one of strict liability. Therefore, Count V is duplicative, just as the Negligence count was duplicative of the claims for design defect and failure to warn. As such, Count V of the Wortmans' Complaint shall be treated as part of the Wortmans' manufacturing defect theory, and that theory shall proceed under the Wortmans' IPLA claim.

would work as expected," and Ms. Wortman "relied upon [Bard's] implied warranties of merchantability and misrepresentations regarding the viability and safety of the Align" device. [Filing No. 1 at 50.] The Wortmans allege that the Align device "was neither merchantable nor suited for its intended use as warranted and promoted by [Bard.]" [Filing No. 1 at 51.]

The Wortmans allege that, as a result of these breaches of warranties, Ms. Wortman has suffered the following damages: "significant mental and physical pain and suffering, . . . permanent injury, loss of consortium, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages." [Filing No. 1 at 51.]

Because the Wortmans concede that these claims are subsumed by the IPLA, and the IPLA is Ms. Wortman's exclusive remedy, Bard's Motion to Dismiss on these claims is **GRANTED**. Ms. Wortmans' sole claim is her IPLA claim, which may be based on "a manufacturing flaw, a defective design or a failure to warn of the dangers while using the product." *Campbell Hausfeld/Scott Fetzer Co. v. Johnson*, 109 N.E.3d 953, 956 (Ind. 2018).

IV.
CONCLUSION

Based on the foregoing, the Court makes the following rulings:

1. Bard's Motion for Oral Argument, [12], is **DENIED**.
2. Bard's Motion to Dismiss, [10], is **GRANTED IN PART** and **DENIED IN PART** as follows:
    a. The Motion is **DENIED** as to the issue of the Wortmans' claims being time-barred by the statute of repose.

b. The Motion is **DENIED as moot** as to the issues of lack of vertical privity and pre-suit notice of breach.

c. The Motion is **GRANTED** as to the Wortmans' claims for Gross Negligence, Unjust Enrichment, and the standalone claim for punitive damages.[7] Those claims are **DISMISSED WITH PREJUDICE**.

d. The Motion is **GRANTED** as to Mr. Wortman being a plaintiff. Mr. Wortman is **DISMISSED WITHOUT PREJUDICE** as a plaintiff**.**

e. The Motion is **GRANTED** as to the Wortmans' Negligent Misrepresentation claim, and that claim is **DISMISSED WITH PREJUDICE**.

f. The Motion is **GRANTED** as to the Wortmans' Negligent Infliction of Emotional Distress claim, and that claim is **DISMISSED WITH PREJUDICE**.

g. The Motion is **GRANTED** as to the Wortmans' claims for Breach of Express Warranty and Breach of Implied Warranty, and those claims are **DISMISSED WITH PREJUDICE**.

h. The Motion is **DENIED** as the Wortman's remaining theories of recovery, which **shall proceed** under an IPLA claim.

The Wortmans may file an Amended Complaint **on or before December 10, 2019** to raise a proper loss of consortium claim on behalf of Mr. Wortman and to revise Ms. Wortmans' IPLA claim in accordance with the Court's findings herein.

[7] This ruling should not be read as a decision on the propriety of a punitive damage recovery, but simply a ruling that there exists no separate cause of action for punitive damages. *See Ford Motor Co. v. Ammerman*, 705 N.E.2d 539, 563 (Ind. Ct. App. 1999) (affirming award of punitive damages against manufacturer in IPLA case).

The Court requests that the Magistrate Judge set a conference with the parties at her earliest convenience to discuss whether limited discovery followed by an early partial summary judgment briefing schedule on the statute of repose issue is advisable.

Date: 11/26/2019

Hon. Jane Magnus-Stinson, Chief Judge
United States District Court
Southern District of Indiana

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